Compliance Policy Guide

Guidance for FDA and CBP Staff

Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

Comments and suggestions regarding this Compliance Policy Guide (CPG) should be submitted to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with docket number 2003D-0554.

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Food and Drug Administration
Office of Regulatory Affairs
Center for Food Safety and Applied Nutrition
Center for Veterinary Medicine

U.S. Department of Homeland Security
Bureau of Customs and Border Protection

December 2003

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This guidance document represents the Food and Drug Administration's (FDA) and Customs and Border Protection's (CBP) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA, CBP, or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

Sec. 110.310: **Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002**

INTRODUCTION:

The purpose of this document is to provide guidance on FDA's and CBP's strategy for enforcing and otherwise achieving compliance with the requirements of the interim final rule for submitting prior notice for food imported or offered for import into the United States (68 Fed. Reg. 58974 (Oct. 10, 2003) (to be codified at 21 CFR 1.276 – 1.285)).

FDA's guidance documents, including this Compliance Policy Guide, do not establish legally enforceable responsibilities. Instead, guidance documents describe the agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in agency guidance documents means that something is suggested or recommended, but not required.

BACKGROUND:

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act), section 307, added section 801(m) to the Federal Food, Drug, and Cosmetic Act (the Act) to require that FDA receive prior notice for food imported or offered for import into the United States. Section 801(m) also provides that if an article of food arrives at the port of arrival with inadequate prior notice (e.g., no prior notice, inaccurate prior notice, or untimely prior notice), the food is subject to refusal of admission under section 801(m)(1) of the Act and may not be delivered to the importer, owner, or consignee. If an article of food is refused under section 801(m)(1) of the Act, unless CBP concurrence is obtained for export and the article is immediately exported from the port of arrival under CBP supervision, it must be held within the port of entry for the article unless directed by CBP or FDA.

The Bioterrorism Act, section 305, also amended Chapter IV of the Act by adding section 415 to require domestic and foreign facilities that manufacture, process, pack, or hold food for consumption in the United States to register with FDA, and amended Chapter VIII of the Act by adding section 801(l) to require any food for human and animal consumption from an unregistered foreign facility that is imported or offered for import to be held at the port of entry until the foreign facility has been registered.

On October 10, 2003, FDA and CBP issued interim final regulations establishing the requirements for registration and requiring that FDA receive prior notice of the importation of food beginning on December 12, 2003 (68 FR 58994 and 68 FR 58974). For the purposes of prior notice, "food" has the meaning given in section 201(f) of the Act, and is defined as (1) articles of food or drink for man or other animals, (2) chewing gum, and (3) articles used as components of any such article, except that it does not include food contact substances or pesticides. The requirements for prior notice do not apply to:

(1) Food for an individual's personal use when it is carried by or otherwise accompanies the individual when arriving in the United States;

(2) Food that was made by an individual in his/her personal residence and sent by that individual as a personal gift (i.e. for non-business reasons) to an individual in the United States;

(3) Food that is imported then exported without leaving the port of arrival until export;

(4) Meat food products that at the time of importation are subject to the exclusive jurisdiction of the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act (21 U.S.C. 601 et seq.);

(5) Poultry products that at the time of importation are subject to the exclusive jurisdiction of USDA under the Poultry Products Inspection Act (21 U.S.C. 451 et seq.); or

(6) Egg products that at the time of importation are subject to the exclusive jurisdiction of USDA under the Egg Products Inspection Act (21 U.S.C. 1031 et seq.).

Information required to be submitted in a prior notice includes, with certain exceptions, the registration numbers assigned to the foreign manufacturer's and shipper's facilities that are associated with the article of food. FDA's monitoring of compliance by foreign facilities with the requirement to register under section 415 of the Act will be accomplished primarily through the prior notice review process. If an article of food is from a foreign manufacturer that is not registered as required and is imported or offered for import, then the food is subject to refusal under section 801(m)(1) of the Act for failure to provide adequate prior notice. Likewise, the failure to provide the correct registration number of the relevant foreign manufacturer, if registration is required, renders the identity of that facility incomplete for purposes of prior notice. In addition, if an article of food is imported or offered for import from any foreign facility that is not registered as required, then the food is subject to being held under 801(l) of the Act.

In the preamble to the interim final rule, FDA stated that it planned to provide guidance to its staff regarding the agency's enforcement policies. FDA also stated its intent to provide a transition period, during which it would emphasize education on the prior notice requirements to help industry achieve compliance with the regulation. Accordingly, this Compliance Policy Guide establishes policies regarding the

enforcement of the prior notice requirements, including the requirement to provide a required registration number.

POLICY:

The requirements for submitting prior notice to FDA are effective beginning December 12, 2003. However, as described below, during the first eight months following this effective date, FDA and CBP plan to focus their resources on education to achieve compliance with the prior notice requirements. While educational efforts will be made in response to specific violations, FDA and CBP also intend to continue their broad, pro-active educational initiatives during the initial eight-month period, including the following:

1. FDA and CBP will distribute information flyers at the ports.
2. FDA and CBP plan to:
    a. Gather data to track compliance with the prior notice requirements and to determine how best to use their resources to educate industry and the public in order to achieve full compliance.
    b. Provide industry and the public with summary information about the level of compliance with the prior notice requirements, including data on the types of errors in submitted prior notices.
    c. Provide the summary information on FDA's website at www.fda.gov.
    d. Utilize the data and summary information to assist the industry and the public in improving the submission of prior notice.

FDA may consider the failure to provide adequate prior notice as a factor in determining whether and where to examine an article of food. However, during this eight-month period and after, if FDA decides not to refuse an article of food under 21 CFR 1.283 or 1.285, this decision has no bearing on whether the article of food is admissible or will be granted admission under other provisions of the Act or other U.S. laws. Thus, for food that is imported or offered for import, FDA will continue its normal review, investigative, and enforcement activities for food safety and security concerns to determine whether the food is subject to refusal under section 801(a) of the Act. In addition, if FDA decides not to refuse an article of food under 21 CFR 1.283 or 1.285, this decision does not affect FDA's ability to initiate other types of actions -- such as seizures, injunctions, prosecutions, or debarments under sections 302, 303, 304, and 306 of the Act -- that may be necessary. Likewise, it does not affect CBP's ability to initiate other types of actions that may be necessary.

REGULATORY ACTION GUIDANCE:

FDA’s Prior Notice Review Center, in conjunction with CBP headquarters, should use the tables below to make decisions about whether to refuse a shipment of food pursuant to 21 CFR 1.283 or 1.285 for violations under sections 801(m) and 415 of the Act.

The following definitions and descriptions apply to the tables.

Types of Violations

A. Inadequate Prior Notice

1. No Prior Notice - The article of food arrives at the port of arrival and no prior notice has been submitted and confirmed by FDA for review.
2. Inaccurate Prior Notice - Prior notice has been submitted and confirmed by FDA for review, but upon review of the notice or examination of the article of food, the prior notice is determined to be inaccurate.
3. Untimely Prior Notice - Prior notice has been submitted and confirmed by FDA for review, but the full time that applies under 21 CFR 1.279 for prior notice has not elapsed when the article arrives, unless FDA has already reviewed the prior notice, determined its response to the prior notice, and advised CBP of that response.

B. Unregistered Facility - The article of food is imported or offered for import from a foreign facility that is not registered as required.

C. No PN Confirmation

1. When a copy of the Prior Notice (PN) Confirmation is required for food carried by or otherwise accompanying an individual, but cannot be provided by the individual.
2. When the PN Confirmation Number is not affixed to an article of food that arrives by international mail.

Categories of Violations

Category 1 Violations - Available credible evidence or information, including information in the prior notice, if any, indicates that the article presents a threat of serious adverse health consequences or death to humans or animals.

Category 2 Violations - The violation:

(a) Reflects a history of repeated conduct of a similar nature by a person who has been notified of such violations; or

(b) Appears to be intentional or flagrant.

Category 3 Violations - All violations other than those that fall within Category 1 or 2.

Actions in Response to Violations

Education/Communication - To the extent possible:

(a) Distribute information flyers at the ports to carriers and others associated with the shipment of food.

(b) Provide, to the extent practicable, notice of the violation and of the prior notice and registration requirements to the person(s) who transmits and/or files the prior notice.

(c) When an article of food that is carried by or otherwise accompanying an individual is not for personal use and has inadequate prior notice or the individual cannot provide FDA or CBP with a copy of the prior notice (PN) confirmation, provide the individual with an information sheet on prior notice.

(d) When an article of food arrives by international mail with inadequate prior notice or the PN confirmation number is not affixed, provide an information sheet on prior notice and forward the package to the addressee.

Assessment of CBP Civil Monetary Penalties - CBP, in consultation with FDA, may assess civil monetary penalties for violation of 19 U.S.C. 1595a(b) against any party who aids or abets the importation of any merchandise contrary to law.

Refusal - FDA, in consultation with CBP, may refuse admission of an article of food under section 801(m)(1) of the Act or place it under hold under section 801(l) of the Act for violations under sections 801(m) and 415 of the Act. If an article of food is refused or placed under hold under these provisions, unless CBP concurrence is obtained for export and the article is immediately exported from the port of arrival under CBP supervision, it must be held within the port of entry for the article unless directed by CBP or FDA. 21 CFR 1.283(a) and 1.285(a), (b). For food that is carried by or otherwise accompanying an individual, and is refused, and if, before leaving the port, the individual does not arrange to have the food held at the port or exported, the article of food shall be destroyed. 21 CFR 1.283(b) and 1.285(h). For food that arrives by international mail and is refused, if there is a return address, the parcel will be returned to sender stamped "No Prior Notice – FDA Refused." If there is no return address, or if FDA determines that the article of food in the parcel appears to present a hazard, FDA may dispose of or destroy the parcel. 21 CFR 1.283(e) and 1.285(k).

Table 1 - Implementing 21 CFR 1.283(a) and 1.285(a), (b). Shipments of food, other than food carried by or otherwise accompanying an individual or food arriving by international mail. Table 1 describes actions FDA and CBP staff typically should consider taking when an article of food is imported or offered for import into the United States with inadequate prior notice. It does not apply to food arriving by international mail or food carried by or otherwise accompanying an individual.

Table 2 - Implementing 21 CFR 1.283(b) and 1.285(h). Food carried by or otherwise accompanying an individual. Table 2 describes actions FDA and CBP staff typically should consider taking when an article of food that is carried by or otherwise accompanying an individual is not for personal use and has inadequate prior notice or the individual cannot provide FDA or CBP with a copy of the PN confirmation.

Table 3 - Implementing 21 CFR 1.283(e) and 1.285(k). Food arriving by international mail. Table 3 describes actions FDA and CBP staff typically should consider taking when an article of food arrives by international mail with inadequate prior notice or the PN confirmation number is not affixed as required.

The phrase "the action FDA and CBP staff typically should consider taking" used in the tables means that FDA and CBP staff, pursuant to their agency's policies and procedures, may take these actions or may take different or additional actions if they believe particular circumstances warrant them.

Table 1: Implementing 21 CFR 1.283(a) and 1.285(a), (b). Shipments of food, other than food carried by or otherwise accompanying an individual or food arriving by international mail.*

If the violation occurs:	and if the violation is due to:	then for violations that fall within Category 3, the action FDA and CBP staff typically should consider taking is:	then for violations that fall within Category 2, the action FDA and CBP staff typically should consider taking is:	then for violations that fall within Category 1, the action FDA and CBP staff typically should consider taking is:
December 12, 2003 to March 12, 2004	(1) No prior notice	Education/ communication. Analysis of data for compliance action.	Education/ communication. Analysis of data for compliance action.	Refusal and possible CBP civil monetary penalties.
	(2) Inaccurate prior notice, untimely prior notice, or an unregistered facility	Education/ communication. Analysis of data for compliance action.	Education/ communication. Analysis of data for compliance action.	Refusal and possible CBP civil monetary penalties.
March 13, 2004 to May 12, 2004	(1) No prior notice	Education/ communication. Analysis of data for compliance action.	Assessment of CBP civil monetary penalties.	Refusal and possible CBP civil monetary penalties.
	(2) Inaccurate prior notice, untimely prior notice, or an unregistered facility	Education/ communication. Analysis of data for compliance action.	Education/ communication. Analysis of data for compliance action.	Refusal and possible CBP civil monetary penalties.
May 13, 2004 to August 12, 2004	(1) No prior notice	Refusal.	Refusal and/or assess CBP civil monetary penalties.	Refusal and possible CBP civil monetary penalties.
	(2) Inaccurate prior notice, untimely prior notice, or an unregistered facility	Education/ communication. Analysis of data for compliance action.	Assess CBP civil monetary penalties.	Refusal and possible CBP civil monetary penalties.
After August 12, 2004	(1) No prior notice	Refusal and/or assess CBP Civil Monetary Penalties.	Refusal and/or assess CBP civil monetary penalties.	Refusal and possible CBP civil monetary penalties.
	(2) Inaccurate prior notice, untimely prior notice, or an unregistered facility	Refusal and/or Assess CBP civil monetary penalties.	Refusal and/or Assess CBP civil monetary penalties.	Refusal and possible CBP civil monetary penalties.

* Definitions and descriptions of the types of violations, categories of violations, and actions in response to violations are given above.

Table 2: Implementing 21 CFR 1.283(b) and 1.285(h). Food carried by or otherwise accompanying an individual.*

If the violation occurs:	and if the violation is due to:	then for violations that fall within Category 3, the action FDA and CBP staff typically should consider taking is:	then for violations that fall within Category 2, the action FDA and CBP staff typically should consider taking is:	then for violations that fall within Category 1, the action FDA and CBP staff typically should consider taking is:
December 12, 2003 to August 12, 2004	(1) Inadequate prior notice or an unregistered facility	Education/ communication.	Education/ communication.	Refusal.
	(2) No PN confirmation	Education/ communication.	Education/ communication.	Refusal.
After August 12, 2004	(1) Inadequate prior notice or an unregistered facility	Education/ communication (minor or inadvertent problems) or refusal.	Refusal.	Refusal.
	(2) No PN confirmation	Education/ communication (minor or inadvertent problems) or refusal.	Refusal.	Refusal.

* Definitions and descriptions of the types of violations, categories of violations, and actions in response to violations are given above.

Table 3: Implementing 21 CFR 1.283(e) and 1.285(k). Food arriving by international mail.*

If the violation is on or after:	**and if the violation is due to:**	**then for violations that fall within Category 3, the action FDA and CBP staff typically should consider taking is:**	**then for violations that fall within Category 2, the action FDA and CBP staff typically should consider taking is:**	**then for violations that fall within Category 1, the action FDA and CBP staff typically should consider taking is:**
December 12, 2003 to August 12, 2004	(1) Inadequate prior notice or an unregistered facility	Education/ communication.	Education/ communication.	Refusal.
	(2) No PN confirmation	Education/ communication.	Education/ communication.	Refusal.
After August 12, 2004	(1) Inadequate prior notice or an unregistered facility	Education/ communication (minor or inadvertent problems) or refusal.	Refusal.	Refusal.
	(2) No PN confirmation	Education/ communication (minor or inadvertent problems) or refusal.	Refusal.	Refusal.

* Definitions and descriptions of the types of violations, categories of violations, and actions in response to violations are given above.